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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,454	10/27/2000	Miri Seiberg	JBP0518	5753
7590	03/28/2006		EXAMINER	
Philip S. Johnson, Esq. Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003				LAMM, MARINA
		ART UNIT	PAPER NUMBER	1616

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,454	SEIBERG ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 December 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15, 16 and 18-22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 15, 16 and 18-22 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment and declaration filed 12/19/05.

Claims pending are 15, 16 and 18-22. Claim 17 has been cancelled.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of Claim 22 under 35 U.S.C. 102(a) as being anticipated by Kelly et al. (WO 99/36050) is maintained for the reasons of the record.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of Claims 15, 16 and 18-21 under 35 U.S.C. 103(a) as being unpatentable over Tokuyama (JP 5-320061) in view of Mizue (JP 62-36304) is maintained for the reasons of the record.

Response to Arguments and Declaration

5. Applicant's arguments filed 12/19/05 have been fully considered but they are not persuasive.
6. With respect to the rejection of Claim 22 as being anticipated by the Kelly et al. reference, the Applicant argues:

"...applicants' claimed invention requires a non-denatured soy product, in which the protease inhibitory activity of the soy product has not been eliminated by processing. The non-denatured state is measured by the presence of an intact soybean trypsin inhibitor (STI) protein. As set forth in the Declaration of Dr. Miri

Seiberg, filed concurrently herewith, it was known at the time of invention that proteins, including soy proteins, are denatured in the presence of ethanol. (Seiberg Declaration, ¶¶3-5). Therefore, they would not have expected the Kelly extract to contain active proteins such as serine protease inhibitors. Thus, they would not have been led to the compositions of applicants' invention through the Kelly reference. Applicants respectfully submit that the soy extract set forth in Kelly is not non-denatured and the recitation of a "non-denatured" soy product is not inherent in Kelly as the Office Actions asserts." See p. 5 of the reply.

In response, Kelly et al. teach that the ratio of organic solvent (e.g. ethanol, chloroform, acetone, ethyl acetate and the like) in water may be as low as 0.1%. It is highly unlikely that 0.1% of ethanol in water will cause protein denaturation. Moreover, the soy extract containing compositions of Kelly et al. possess the same skin protecting activity as claimed herein, which indicates that the protease inhibitory activity of the soy product has not been eliminated by the extraction process.

7. The declaration of Miri Seiberg, Ph.D., filed 12/19/05, is insufficient to overcome the rejection of claim 22 based upon Kelly et al. as set forth in the last Office action for the following reasons: **(1)** the statements in the Declaration are too broad and generic. More specifically, the Declarant asserts that "[t]hose knowledgeable about protein activity at the time the invention was made were aware that proteins are denatured in the presence of ethanol". See ¶3 of the declaration. This statement raises some questions: Would all proteins, regardless of their structure, be denatured by ethanol? Would ethanol denature proteins at any concentration? Would the exposure time make a difference? Would this specific protein (STI) be denatured by ethanol and at what concentration? **(2)** the reference teaches using organic solvents other than ethanol for extracting soybeans.

Art Unit: 1616

8. With respect to the rejection of Claims 15-21 as being obvious over Tokuyama (JP 5-320061) in view of Mizue (JP 62-36304), the Applicant argues:

"Applicant respectfully submits that the invention of Tokuyama is different from that in instant application. Tokuyama did not recognize the importance of maintaining the STI activity and is not concerned that the extract retain (sic!) serine protease inhibitory activity. Rather, Tokuyama uses heat and extraction procedures which are known to denature proteins, thereby eliminating protease inhibitory activity." See pp. 6-7 of the reply.

In response, the Tokuyama reference teaches the same extraction method as disclosed in the instant application. See Examples 2 and 3. Therefore, the soy product of Tokuyama is non-denatured because it is produced by the same method as disclosed herein. The fact that the Applicant has recognized the importance of some properties of the composition/product of the prior art does not have a bearing on the patentability of the claimed method if the claimed method was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

9. In response to Applicant's argument that there is no suggestion to combine the references (see p. 7 of the reply), the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this

case, the Tokuyama reference does not explicitly teach the stabilizing system of the instant claims. However, Mizue teaches stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA as discussed previously. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cosmetic or dermatological soy extract-containing compositions of Tokuyama such that to add chemical agents such as preservatives. One having ordinary skill in the art would have been motivated to do this to prevent spoilage of the soy extract as suggested by Mizue. The strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144.

10. With respect to the Applicant's request for clarification as to the Mizue reference (see p. 6 of the reply), it is noted that the title and inventor's name of JP 62-36304 was copied from the official USPTO translation document, the copy of which was sent to the Applicant on 6/28/01.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

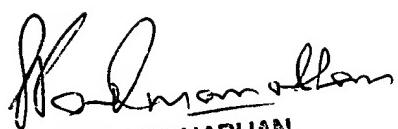
The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1616

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
3/19/06


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER